UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LIGITATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ALL CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

DECLARATION OF PAMELA DOWNS

Pamela Downs deposes and says:

1. My name is Pamela Downs. I am over twenty-one years of age and of sound mind. I am competent to testify about all of the matters set out in this Declaration.

2. I am employed as a Senior Director at Epiq Systems, Inc., eDiscovery and Litigation Solutions. During my 26 year career supporting the legal services industry, I have extensive experience in the assessment, collection and production of hard copy and electronically stored information in litigated matters.

3. In January 2013, on behalf of Ethicon, Inc. ("Ethicon"), I was retained to investigate the nature and scope of documents outside of the United States ("ex-US documents") maintained by Ethicon, along with the associated burdens to collect them with respect to the products at issue in this litigation.

4. During the course of my investigation, I have interviewed approximately 60 persons. I have conducted these interviews in connection with preparation for the Fed. R. Civ. P. 30(b)(6) deposition concerning ex-US documents.

5. I have focused my investigation primarily upon the following categories of documents: regulatory, professional education, marketing, sales training, public relations, copy approval, design and development, pre-clinical studies, clinical trials, post market surveillance, global records management, legal hold management, health care compliance, and labeling.

6. I have also reviewed the following documents during the course of my investigation: Regulatory Affairs International Country Listing, Operating Procedure 608-012 regarding Copy Approval, Policy 553-005 For Records Management, Form Use Instructions 0001698 regarding Records Inventory Indexing, Process Specification 0000117 regarding Onsite Paper/Electronic Records Clean-up, 11 relevant Legal Hold Notices, Production Letters from LeClairRyan, and Custodian Sources Listing In Re: Ethicon, Inc. Pelvic Floor Repair System, Product Liability Litigation.

7. Based on the information that I have been provided, it is my understanding that the 15 products at issue in this litigation are sold in approximately 190 countries and regulated in 67 countries. There are approximately 915 separate regulatory filings and approvals (this does not included renewals) ex-US for the 15 products. For example, the TVT "Classic" product has received regulatory approval in approximately 67 countries. TVT AA has received regulatory approval in approximately 56 countries. TVT Abbrevo has received regulatory approval in approximately 61 countries. TVT Exact has received regulatory approval in approximately 61 countries. TVT O has received regulatory approval in approximately 60 countries. TVT Secur has received regulatory approval in approximately 61 countries.

8. Based on my investigation, I have determined that for products sold in countries other than the United States, unique documents relating to those products, such as regulatory,

marketing and professional education documents, are generally stored in the country of origin. I have further determined that those unique documents are not aggregated in a central repository.

9. I have also found that many documents used in countries other than the United States, such as marketing materials, are simply translated or slightly modified (e.g. to include local contact information) versions of materials that are used in the United States.

10. Generally speaking, to globally collect ex-US documents would be a massive, 190+ country undertaking for all countries and a 67 country undertaking for regulated countries. As stated, there is no central repository that maintains these documents. Instead, to collect the documents would require locating a knowledgeable subject matter point of contact for each particular document category, in 190 or 67 countries. For each document category or subject area, whether it be regulatory, marketing or something else, the point of contact will almost always be different. Once that point of contact is established, that person or persons must then locate the relevant documents that could be stored in, for example, South Africa. Once those documents are located, they then must be collected and sent to the United States for review and production. This repetitive process would be generally required for each document category or subject matter in each country.

11. By way of example, for Australia, I spoke to five different individuals regarding documents in the following subject areas: Regulatory, Professional Education, Marketing and Sales Training. Also, based upon information I was provided by in-house counsel and the Epiq Systems' collection consultants, they spoke to thirteen additional individuals to collect 56 megabytes of unique Marketing documents and one website. For Japan, I spoke to three different individuals regarding documents in the following subject areas: Regulatory, Professional Education, Marketing and Sales Training. The Epiq Systems' collection consultants

spoke to three additional individuals to collect the unique Marketing documents and one website from Japan.

12. I have also been asked to provide examples of the voluminous ex-US documents that have been produced. Below are my conclusions based on reviewing the contents of Ethicon's production.

13. Ethicon has produced the custodial files of approximately 52 ex-US custodians that totals nearly 250,000 documents.

14. Ethicon has produced relevant documents from numerous ex-US central sources and databases, including Norderstedt ACMS Agile (including Neuchatel Agile), EU Clinical Research Data Entry Group Share, EU Health Care Compliance Group Share, UK 522 Order Group Share, UK TMF Paper Files, and UK Trial Master File Group Share.

15. Many other categories of ex-US documents have been produced. Although certainly not exhaustive, below are additional examples:

- The International Regulatory SharePoint was previously produced on October 1, 2012. This is the vehicle used by U.S. Regulatory Affairs to communicate with international employees completing international regulatory filings.
- The Agile IFU repository containing materials distributed outside of the United States was produced on March 30, 2012 and the GGM Blue marketing repository was produced on December 30, 2011 and February 15 and 17, 2012 .
- The custodial files of the Europe, Middle East and Africa Marketing Manager and the Latin America Marketing Manager were previously produced.
- With very few exceptions, all international sales representatives were trained in the US and the US sales training group share and other information was previously produced on February 23, 2012 and March 2, 2012.
- Investigator Studies maintained in the United Kingdom were produced August 7, 2012.

- All of the product registries also maintained in the United Kingdom were produced on August 7, 2012.

16. Ethicon has also produced the worldwide adverse events for the products at issue.

17. During the meet and confer process concerning ex-US documents, Plaintiffs specifically requested regulatory documents from three countries: Japan, France and Australia. Because regulatory documents are not stored in a central location, but in the country of origin, this required Ethicon to work with persons in each of these countries to locate and collect these documents. Additionally, with respect to Japan and France, this required extensive and costly translations.

18. Plaintiffs also requested that Ethicon produce marketing materials for the products at issue from 32 separate countries. Ethicon has produced unique marketing materials located from these 32 foreign countries.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this the 2nd day of June, 2013.

Pamela Downs

PAMELA DOWNS